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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/143,143 | 08/28/98 | ASH S | 37011-6 |

HM22/0518

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| EXAMINER | |
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| PAK, J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | 11 |

**DATE MAILED:** 05/18/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

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# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/143,143 | ASH |
| **Examiner** | **Group Art Unit** |
| John Pak | 1616 |

☒ Responsive to communication(s) filed on *Jan 31, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *24-45* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *24-45* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

Claims 24-45 are pending in this application.

Claims 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 40 reads "[a] method of making an aqueous composition useful as a dialysate ... to provide a **second** aqueous solution" (emphasis added). The preamble recites making a dialysate (or concentrate), but the claim ends by making a "second aqueous solution." There is a need for some kind of a nexus between the claim preamble and the product obtained at the end of the claim so that they correspond to each other.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24 and 26-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mulchandani et al. (US 5,108,767).

Mulchandani et al. expressly disclose an aqueous composition that meets all of the composition requirements of the instant claims. In Table I, column 5, Mulchandani et al. explicitly disclose a multi-ingredient aqueous composition that contains, inter alia, various electrolytes, including ferrous sulfate. In Table II, column 7, Mulchandani et al. explicitly disclose that their aqueous formulation provides 18.9 mg of iron/liter and has milliequivalents of electrolytes that are within the range of the instant claims.

Therefore, all claim limitations of instant claims 24 and 26-30 are specifically met by Mulchandani's aqueous composition. The claims are thereby anticipated, or at the very least rendered obvious within the meaning of 35 USC 103(a) as every element of the claimed composition is explicitly disclosed by Mulchandani's aqueous composition.

Claims 24-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellini et al. (EP 612,528) in view of the acknowledged prior art and Martindale The Extra Pharmacopoeia (hereinafter, Martindale).

Bellini et al. disclose solutions for peritoneal dialysis that contain electrolytes (at the milliequivalent range required in the instant claims), gluconate salt such as iron gluconate and glucose. See from page 2, line 43 to page 4, line 46. Concentrates and diluted forms are disclosed (page 4, lines 44-46).

Applicant admits the following in the specification:

(1) iron deficiency is commonly encountered in pregnancy and in various disease states such as end stage renal disease (page 2);

(2) oral iron supplementation with substances such as ferrous gluconate, ferrous citrate, ferrous sulfate, ferrous fumarate, and ferric polysaccharide complexes is known (page 3, first paragraph); and

(3) intraperitoneal delivery of iron dextran is known (page 6, first full paragraph).

Martindale discloses iron compounds and products that are known for treating iron deficiency (page 976). Ferrous fumarate, ferrous gluconate, ferrous succinate and ferrous sulfate are disclosed, as well as ferrous gluconate + calcium (pages 976, 1596 (see Ferro-C-Calcium))

The difference between the claimed invention and the cited prior art is that the prior art does not explicitly disclose in a single specific example the combination of electrolytes and "iron complex" and method for making an aqueous formulation wherein the electrolytes are first prepared at a predetermined milliequivalent level before adding the iron complex.

However, it is known that chronic dialysis patients often require iron supplementation; and Bellini's dialysate formulation may contain ferrous gluconate. Given the known use of ferrous gluconate and other iron compounds in oral iron supplementation, taken with the known intraperitoneal delivery of an iron substance, one having ordinary skill in the art would have been particularly motivated to utilize ferrous gluconate as the gluconate species in Bellini's dialysate formulation to treat dialysis patients who are in need of iron supplementation.

As for the claimed method of making the compositions by preparing electrolytes at a predetermined (223–12,940 mEq/l) milliequivalent level before adding the iron complex, such process steps are seen to be well within the skill of the ordinary skilled artisan who would have been capable of arriving at the necessary iron content and electrolyte concentration via various mixing order of the ingredients.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Applicant's remarks filed in the response of 1/31/00 have been given due consideration in this regard, to the extent that they are relevant to this new ground of rejection, but much of the arguments therein are negated by the new reference by Bellini et al. There, ferrous gluconate is clearly disclosed in solutions to be used for dialysis; and the Examiner has established from the acknowledged prior art and Martindale that the ordinary skilled artisan would have recognized the use of ferrous gluconate in Bellini's formulation not only as an osmotic component but also as an iron supplementing component.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A **timely filed terminal disclaimer** in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,906,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is overlap in the compositions of this application and the claimed composition of the patent; and the claimed method for making the compositions by first providing a predetermined concentration of electrolytes is held to be within the skill of the ordinary skilled artisan who would have been capable of arriving at the necessary iron content and electrolyte concentration via various mixing order of the ingredients.

For the foregoing reasons, all claims are rejected again.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1200